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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,117	07/31/2003	Hilda Elizabeth Smith	2183-6055US	5350

24247 7590 09/27/2006

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,117	SMITH, HILDA ELIZABETH	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-15* is/are pending in the application.

4a) Of the above claim(s) *1,6,7 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed July 7, 2006 has been entered. Claims 1, 9 and 11 have been amended. Claims 2-5, 8, 10 and 16-20 have been cancelled. Claims 6-7 and 9 have been withdrawn from consideration. Claim 11-15 are pending in this office action.

Response to Arguments

2. Applicant's arguments filed July 7, 2006 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The written description rejection of claims 11-15 under 35 U.S.C. 112, first paragraph, is maintained for reasons already of record.

Applicants' urge that the structure of the isolated or recombinant nucleic acid molecules would be clear to one of ordinary skill in the art based on the description SEQ ID NO:37. While is clear that the SEQ ID NO: 37 has been identified, applicants still have not described the isolated or recombinant nucleotide sequence which may encompass small fragments that are capable of hybridizing to the full length of a nucleotide sequence SEQ ID NO: 37. There is no requirement that the entirety of the claimed molecule hybridize to the full length of SEQ ID NO:37. Thus applicants were not

in possession of the isolated or recombinant nucleic acid molecules which hybridize to SEQ ID NO:37. There are no experiments which show the isolation or recombinant making of a nucleic acid molecule which is capable of hybridizing as instantly claimed. There are no vectors, host cells or compositions which comprise the isolated or recombinant nucleic acid molecule fragments. It is noted that possession of SEQ ID NO: 37 does not equate to possession of an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin comprising: a nucleotide sequence capable of hybridizing to the full length of SEQ ID NO: 37 which hybridizes at the recited conditions. Thus, Applicants arguments are not found persuasive.

As previously stated, the specification does not place any structure, chemical or absolute functional limitations on the nucleic acid molecule per se. The recitation of a nucleic acid molecule does not convey a common structure or function. The scope of the claims includes numerous structural variants and the genus is highly variant because a significant number of structural differences between the genus members are permitted. The specification fails to provide guidance on the structure of the nucleic acid molecules. Structural features that could distinguish molecules in the genus from others in the class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. It is noted that the nucleic acid molecule only be capable of hybridizing. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. The skilled artisan cannot envision the detailed structure of an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin as instantly recited, thus

conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

Even where there is an actual reduction to practice, it does not necessarily describe what the claimed invention is. The instant claims describe a nucleic acid molecule described by its function i.e., the capability of hybridization, however this description does not describe the claimed nucleic acid molecules themselves. See also, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), where the court held that a generic statement that defines a genus of nucleic acids by only their functional activity does not provide an adequate description of the genus. The court indicated that while applicants' are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it.

One skilled in the art would reasonably conclude that the disclosure fails to provide a representative number of species when the claims provide no structure to the described claimed genus. Applicants were not in possession of the claimed genus because the specification does not convey to one of skill in the art a representative number of nucleic acid molecules as instantly claimed. Thus the specification lacks written description for the claimed invention and full breadth of the claims fails to meet

the written description provision of 35 USC 112, first paragraph. Moreover, one skilled in the art would not recognize that applicants had possession of the claimed isolated or recombinant nucleic acid molecules. Therefore, applicants' arguments were not persuasive and the rejection is maintained.

4. The enablement rejection of claims 11-15 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained. The rejection is on the grounds that the specification fails to identify an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin comprising: a nucleotide sequence capable of hybridizing to the full length of the nucleotide sequence of SEQ ID NO: 37; wherein the hybridizing occurs at 65°C in a buffer having 0.5M sodium phosphate, 1mM EDTA and 7% sodium dodecyl sulphate at a pH of 7.2.

Applicants' urge that paragraph [0066] describes using SEQ ID NO:37 as a probe to identity a chromosomal DNA of *S. suis*. However this section fails to provide an enabling disclosure drawn to an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin comprising: a nucleotide sequence capable of hybridizing to the full length of the nucleotide sequence of SEQ ID NO: 37 at the instantly recited conditions. There is no teaching of isolated or recombinant nucleic acid molecules from *Streptococcus agalactiae, S. bovis, S. equi, S. pneumoniae, S. pyogenes, S. thermophilus* or *Viridans Streptococci* hybridizing at the recited conditions. There is no disclosure of any of these nucleic acid molecules being comprised within a vector, host cell or composition. Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. Such need for non-routine experimentation demonstrates

that the specification is not enabled for any asserted use or well-established use of an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin.

Applicants' also urge that SEQ ID NO:37 is not only capable of hybridizing with nucleic acids of *S. suis* serotype 2 but with a large number of *S. suis* strains of other serotypes. Applicants' point to paragraph [0079] as providing a working example of an isolated or recombinant nucleic acid molecule, and state that one of ordinary skill in the art would be able to make and use the instantly claimed isolated or recombinant nucleic acid molecule without undue experimentation. However this paragraph is drawn to cloning the *S. suis* fibronectin binding protein. There is no teaching of hybridization occurring at 65°C in a buffer having 0.5M sodium phosphate, 1mM EDTA and 7% sodium dodecyl sulphate at a pH of 7.2.There is no teaching that the claimed nucleotide sequence hybridized to the full length of SEQ ID NO:37. Therefore, the specification fails to enable an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin as instantly claimed because the specification fails to teach the identity of such sequences. Thus, Applicants arguments are not found persuasive.

Therefore the specification lacks any written description of a structure or relevant identifying characteristics of a representative number of nucleic acids sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. In absence of further guidance, the skilled artisan would have to discover what the appropriate nucleic acid molecules would be. Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. Such need for non-routine experimentation demonstrates that the specification is not enabled for any

asserted use or well-established use of an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin. No working examples are shown containing the missing information. Accordingly, one of skill in the art would be required to perform undue experimentation to use any nucleic acid at any location to produce such a nucleic acid molecule, thus the rejection is maintained. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

New Grounds Of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element in claim 11 is that the claim omits the essential wash criteria. Therefore clarification is required to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 11-12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by 1997/1998 Stratagene catalog (page 118, 1997/1998).

The claims are drawn to an isolated or recombinant nucleic acid molecule of Streptococcus origin comprising: a nucleotide sequence capable of hybridizing to the full length of the nucleotide sequence of SEQ ID NO: 37; wherein hybridization occurs at 65°C in a buffer having a 0.5M sodium phosphate, 1mM EDTA and 7% sodium sulphate at a pH of 7.2 and a composition comprising the nucleic acid molecule.

The Stratagene catalog teaches a kit comprising a collection of random primers. The collection comprises a multitude of isolated and purified nucleic acid molecules (i.e., primers), each of which consists of 6 nucleotide residues. The collection comprises nucleic acid molecules having every possible 6-nucleotide sequence of the four different nucleotide residues (i.e., A, C, T, and G) of which DNA is comprised. The Catalog also teaches the use of probe vectors and isolating the DNA away from the vector, thereby disclosing a vector comprising the nucleic acid molecule. Therefore, the kit comprises an isolated nucleic acid molecule consisting of a polynucleotide sequence that is, itself, fully complementary to a nucleotide sequence of a nucleic acid molecule having SEQ ID NO: 37.

Because the claims are drawn to an isolated or recombinant nucleic acid molecule of Streptococcus origin comprising a nucleotide sequence which is capable of hybridizing to the full length of the nucleotide sequence of SEQ ID NO: 37, and there is no limitation on the isolated or recombinant nucleic acid molecule's structure or size, the

random primer contained in the kit, the disclosure of the kit and its contents is anticipatory of the presently claimed invention.

Thus, the Stratagene reference teaches hexanucleotides containing all possible 6-nucleotide sequences that would be capable of hybridizing under the recited stringent conditions to SEQ ID NO:37.

Conclusion

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, A. Mark Navarro can be reached on 571-272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
September 13, 2006